



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,810	09/19/2006	David L. Kaplan	5363-3259	4571
21125 7590 07/29/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER MACAULEY, SHERIDAN R				
ART UNIT		PAPER NUMBER		
1651				
NOTIFICATION DATE		DELIVERY MODE		
07/29/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary

Application No.

10/536,810

Applicant(s)

KAPLAN ET AL.

Examiner

SHERIDAN R. MACAULEY

Art Unit

1651

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 119-123 and 125-169 is/are pending in the application.
- 4a) Of the above claim(s) 135 and 137-169 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 119-123, 125-134 and 136 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A response and amendment have been received and entered on March 21, 2008 and March 26, 2008. Claim 124 has been cancelled. Claims 119-123 and 125-169 are pending. Claims 135 and 137-169 have been withdrawn from further consideration due to a previous requirement for restriction. Claims 119-123, 125-134 and 136, insofar as they read upon the elected species, are examined on the merits in this office action.

Claim Rejections - 35 USC § 112

1. Rejections under 35 USC 112 have been withdrawn due to amendment.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1651

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 119-123, 125-134 and 136 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kuczkowski (Rubber Chemical Technology, 1984, 621-651, cited in IDS) in view of Vermeiren (Trends in Food Science and Technology, 1999, 10:77-86), Yan et al. (Biotechnology Letters, 1999, 21:1051-4) and Kobayashi (Chem. Rev. 2001, 101:3793-3818, cited in IDS). Claim 119 recites a method for enzymatically synthesizing a functionalized polymer comprising: coupling an antioxidant to each of a plurality of monomers; and, enzymatically polymerizing the antioxidant-coupled monomers to form an antioxidant-coupled functionalized polymer; whereby the resultant functionalized polymer has inherent antioxidant capabilities. Claim 120 and 121 recite the method of claim 119, wherein the step of coupling an antioxidant to each of a plurality of monomers is carried out such that the resultant polymer has at least 1%, or 10%, of its monomeric units functionalized with antioxidants. Claim 122 recites the method of claim 119, wherein the method further comprises coupling at least one antioxidant per monomer. Claim 123 recites method of claim 119, wherein the method

further comprises using a vinyl monomer. Claim 124 recites the method of claim 119, wherein the step of coupling an antioxidant to each of a plurality of monomers further comprises using an enzyme. Claims 125-128 recite the method of claim 124, wherein the step of coupling an antioxidant to each of a plurality of monomers further comprises selectively acylating primary hydroxyl groups, wherein the method further comprises enzymatically coupling a primary hydroxyl group of the antioxidant to the monomer, or wherein the step of enzymatically coupling an antioxidant to each of a plurality of monomers further comprises selecting an enzyme from the group consisting of proteases, glycosidases, and lipases, specifically a *Candida antarctica* lipase. Claims 129 and 130 recite the method of claim 119 wherein the antioxidant is ascorbic acid, specifically wherein the step of coupling an antioxidant to each of a plurality of monomers further comprises coupling ascorbic acid to the monomers. Claim 131 recites the method of claim 119, wherein the method of enzymatically polymerizing the antioxidant-coupled monomers further comprises using horseradish peroxidase (HRP). Claims 132 and 133 recite the method of claim 119, wherein the method further comprises casting the polymer into a shaped form, specifically a film. Claim 134 recites the method of claim 119, wherein the method further comprises selecting a monomer that is biodegradable. Claim 136 recites the method of claim 119, wherein the method further comprises selecting a single type of monomer and the step of polymerizing the antioxidant-coupled monomers into an antioxidant-coupled polymer further comprises forming an antioxidant-coupled homopolymer.

6. Kuczkowski teaches a method for the production of a functionalized polymer with antioxidant capabilities wherein the antioxidant is coupled to a monomer (a vinyl; p. 628, par. 2 and following reaction scheme). The reference does not specifically teach the use of an enzyme in the coupling of the antioxidant to the monomer or in the polymerization of the polymer.
7. Vermeiren teaches that the integration of ascorbic acid (vitamin C) into polymer films is desirable for the production of food packaging materials (p. 83, par. 1).
8. Yan teaches a method for coupling an antioxidant (ascorbic acid) to a vinyl ester using an enzyme, specifically *C. antarctica* lipase (CAL; abstract, p. 1052, fig 1). In the method of Yan, the primary hydroxyl group of the antioxidant is coupled to the vinyl ester (p. 1052, fig. 1).
9. Kobayashi teaches a method for enzymatically polymerizing monomers to form polymers using horseradish peroxidase (HRP; see p. 3797, par. 1-3, for example).
10. At the time of the invention, a method for the production of a functionalized polymer was known in the art, as taught by Kuczkowski. It was further known in the art that the primary hydroxyl group of an antioxidant such as ascorbic acid could be coupled to a vinyl ester, which may comprise a monomer, using an enzyme such as CAL, as taught by Yan. Polymerization of monomers using HRP was also known at the time of the invention, as taught by Kobayashi. One of ordinary skill in the art would have been motivated to combine the teachings discussed above because Kuczkowski teaches polymer-bound antioxidants are desirable for the production of stabilized polymers. Yan and Vermeiren discuss that the use of vitamin C as a food additive or

Art Unit: 1651

polymer film for food packaging, respectively, is preferential to the use of synthetic antioxidants such as BHT and BHA (Vermeiren p. 83, par. 1 and Yan p. 1051, par. 1). One would therefore have recognized that it would be desirable to produce a polymer-bound vitamin C for use as a polymer film for food packaging. The use of the CAL and HRP enzymes for the synthesis of monomers and polymers, respectively, was also known at the time of the invention. Yan teaches that the use of CAL is preferential to other organic synthesis reactions using ascorbic acid because it reduces the formation of undesired byproducts (p. 1051, par. 4). Kobayashi teaches that the use of biological catalysts, such as HRT, for polymer synthesis is desirable because it allows for more precision in polymerization (p. 3793, par. 1-2). One of ordinary skill in the art would therefore recognize that these enzymes would be useful in the production of an antioxidant-bound polymer. The production of a polymer, specifically a homopolymer, wherein greater than 1 or 10% of the monomers are functionalized, wherein primary hydroxyl groups are acylated, or wherein a biodegradable monomer is selected, would have been a routine matter of experimentation to one of ordinary skill in the art. One of ordinary skill in the art would have had a reasonable expectation of success in combining the teaching discussed above to practice the claimed invention because the synthesis steps set forth in the method were known in the art and were known to be useful with the claimed components. It would therefore have been obvious to one of ordinary skill in the art to combine the references discussed above to arrive at the claimed invention.

11. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

12. Applicant's arguments filed March 21, 2008 and March 26, 2008 have been fully considered but they are not persuasive. Applicant argues that there is no teaching or suggestion in the cited references that would lead one of ordinary skill in the art to combine the teachings of the prior art to arrive at the claimed invention. Applicant further argues that the Yan reference teaches away from the claimed invention because the approach used by the reference differs from that of applicant's invention. Applicant also argues that, due to the unpredictability of applicant's field of endeavor, one of ordinary skill in the art would not have a reasonable expectation of success in combining the teachings of the prior art to arrive at applicant's claimed invention.

13. In response to applicant's argument that there is no teaching or suggestion in the cited references that would lead one of ordinary skill in the art to combine the teachings of the prior art to arrive at the claimed invention, it is noted that the motivation to combine the references has been provided above. Briefly, one of ordinary skill in the art would have been motivated to combine the teachings because polymer-bound antioxidants were known to be desirable at the time of the invention for the production of stabilized polymers, as taught by Kuczkowski. It was further known that vitamin C was a preferred antioxidant for use as a food additive or in a polymer film for food packaging, as taught by Yan and Vermeiren, respectively. One would thus have recognized that it

would be desirable to produce a polymer-bound vitamin C for use as a polymer film for food packaging. The use of the CAL and HRP enzymes for the synthesis of monomers and polymers, respectively, was also known at the time of the invention. Yan teaches that the use of CAL is preferential to other organic synthesis reactions using ascorbic acid because it reduces the formation of undesired byproducts. Kobayashi teaches that the use of biological catalysts, such as HRT, for polymer synthesis is desirable because it allows for more precision in polymerization. One of ordinary skill in the art would therefore recognize that these enzymes would be useful in the production of an antioxidant-bound polymer. Thus, the motivation to produce a vitamin C-bound polymer, specifically by the method of the claimed invention, was present in the prior art at the time of the invention and applicant's argument is not found to be persuasive.

14. In response to applicant's argument that the Yan reference teaches away from the claimed invention because the approach used by the reference differs from that of applicant's invention, it is noted that Yan teaches that the CAL enzyme is preferential to other organic synthesis reactions using ascorbic acid because it reduces the formation of undesired byproducts. Although Yan's approach may differ from that used in the instant reference, either because the reference does not teach the incorporation of the product into a polymer or because the reference does not teach the synthesis of the monomer used in the claimed invention, one of ordinary skill in the art would still recognize that the teachings of Yan would still be relevant to the production of a vitamin-C bound monomer, which one of ordinary skill in the art would have found to be desirable based on the cited teachings discussed above. Since Yan teaches the

desirability for the use of CAL enzymes in organic synthesis reactions using ascorbic acid, one would have been motivated to use the enzyme to produce a monomer for use in the method that is rendered obvious by the cited reference. Thus, applicant's argument that Yan teaches away from the claimed invention and that the teachings of Yan are not pertinent to the claimed invention is not found to be persuasive.

15. In response to applicant's argument that, due to the unpredictability of applicant's field of endeavor, one of ordinary skill in the art would not have a reasonable expectation of success in combining the teachings of the prior art to arrive at applicant's claimed invention, it is noted that one of ordinary skill in the art would have had a reasonable expectation of success in combining the teaching discussed above to practice the claimed invention because the synthesis steps set forth in the method were known in the art and were known to be useful with the claimed components. For instance, reactions using ascorbic acid and CAL were known in the art at the time of the invention, as were reactions using HRP for polymerization. Applicant asserts that Yan teaches away from the instant invention because the reference teaches that lipase-catalyzed synthesis of vitamin C esters had been hampered by long reaction times and the use of solvent. However, the passage by Yan that applicant cites is a statement of the problem that the teachings of Yan attempt to solve. Thus, Yan is referring his own contribution to the state of the art, the teachings of which are relied upon to show that one of ordinary skill would have had a reasonable expectation of success in arriving at the claimed invention. Applicant's argument is therefore not found to be persuasive.

16. Therefore, applicant's arguments have been fully considered, but they are not found to be persuasive.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **SHERIDAN R. MACAULEY** whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone

Art Unit: 1651

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

SRM